December 23, 1999 For Action

New Project

Board on Agriculture and Natural Resources
Commission on Life Sciences

SUMMARY DATA

PIN: TBD

Environmental Impacts Associated with Commercialization of Transgenic Crops.

Board on Agriculture and Natural Resources
Board on Biology

SCOPE

The sub-committee will review the scientific basis for decision-making by the USDA's Animal and Plant Health Inspection Service in response to petitions for determination of non-regulated status for transgenic crops under the authorities of the Federal Plant Pest Act and the National Environmental Policy Act. The sub-committee will look at the scope of the scientific review to assure its relevance and comprehensiveness as regards the products currently being evaluated. The sub-committee will evaluate the appropriateness of the methodologies, the type and quality of data, and the adequacy of issues assessed in these documents. And, finally, potential types of products and issues that should be monitored at commercial scale use will be identified. The sub-committee will not focus on critiquing specific regulatory decisions, but rather, will evaluate current methods, identify gaps, and recommend any needed changes in the overall environmental assessment.

PROPOSED PLAN OF ACTIVITY

The NRC Board on Agriculture and Natural Resources (BANR) and the Commission on Life Sciences proposes to conduct a study that will review the scientific basis underpinning determination of nonregulated status regarding transgenic plant products and to evaluate the scope and adequacy of the APHIS' review of environmental issues.

The study will be conducted by a sub-committee whose members will be drawn from such areas as scientific risk assessment, entomology, plant pathology, weed science, ecology, population biology, horticulture, forestry, plant breeding, evolutionary biology, plant biology, molecular biology, statistics, mathematics, or areas with the required expertise.

Activities of the BANR and the Board on Biology will be coordinated. Significant effort will be made throughout the study to solicit input and provide opportunities for public comment, through mechanisms such as public forums in conjunction with scientific meetings and specific requests for information from interested agencies, organizations and individuals.

USDA will be informed through progress reports at 90 day intervals throughout the course of the study by the NRC on the status of the project. An in-person progress report will occur on or shortly after the first 90-day period from the time this subcommittee is established. (Please note that NRC policy requires that findings, conclusions, and recommendations of the study cannot be provided to the sponsor until the committee's written report has satisfied NRC review requirements.)

Study activities will include a comprehensive review of the scientific literature, APHIS documents and other relevant sources of information regarding risks associated with crop plants in general, transgenic plants specifically, and particular types of transgenic plants as well as approaches to assessment and evaluation of those risks. The evaluation will look at the scientific premises underpinning regulatory evaluation, the process of genetic engineering, and approaches to verifying conclusions and decisions. Particular emphasis will be placed on effects on non-target organisms and provision of guidance on the assessment of non-target effects, including guidance on appropriate tests for environmental evaluation. In addition, guidance on assessment of cumulative effects on the environment will be provided.

Scientific Basis of Environmental Evaluation.

The major focus of the study is to answer the following: 1) Is APHIS asking the right questions? 2) Is APHIS asking for the right data? 3) Is APHIS analyzing the data and information correctly? The study should include a review of the broad general issues; issues with categories of products; and specific issues with specific products. An example of a broad issue would be the impact on biodiversity. Issues associated with virus resistance would be an example of a general product category.

Depending upon the case, a wide variety of information is reviewed and specific data to address specific issues may be requested. In order to put any potential or observed phenomena into

perspective, a critical issue is the establishment of a baseline for comparative purposes. The use of crop plants bred by other means with similar phenotypes has been the general baseline for comparison in making determinations as to safety or risk. Do we have the necessary information regarding the behavior of non-engineered crops? At what point does the reliance on similarity begin to break down? Are the criteria for evaluation appropriate at the various levels of evaluation including: genetic, metabolic, organismal, and ecological. Are there categories of products in which data requirements can be spelled out explicitly or should data requirements continue to be described in a case-by-case fashion? Are the issues of concern comprehensive and addressed appropriately?

There are specific risks associated with any new plant variety. There is a need to determine whether any risks that occur with a variety that has been engineered with a new trait are greater than those risks associated with a variety developed through other means--means which have been accepted as having a history of safe use. Of the types of products being currently developed, are there any concerns with these traits and plant/trait combinations? If so, are those concerns manifested differently in certain types of engineered plants than in similar non-engineered plants with similar or the same traits?

Genetic Engineering Process. The study will review assumptions about the process of genetic engineering. Even though there is much public concern over the use of genetically modified plants in the environment, it still is assumed that the process of genetic engineering *per se* creates no new risks. Because a plant has been genetically engineered, is there any more inherent risk than a plant developed by other means? Does it still hold that the process of genetic engineering presents no new risks *per se*? Are there any unique safety issues associated with transformation and techniques?

Verification. Ongoing consideration of the types of information and confirmation of conclusions is critical to maintain the credibility of the regulatory review and facilitate the appropriate evolution of the regulatory evaluation process. Thus, the sub-committee should address certain concerns such as: 1) Are the data requirements sufficient to justify the conclusions and determinations? 2) What types of monitoring after commercialization might be needed to verify important conclusions at commercial scale? 3) Are there unique safety concerns for products of biotechnology in relation to agriculture in general? Any recommendations concerning monitoring should also be related to concern for specific impacts.

The study will not consider social science issues except where unavoidable. The study will not evaluate the regulatory review process itself, including procedural or decision-making processes.

BACKGROUND

The U.S. regulatory system for review of field testing and environmental release of transgenic plants has been in place for over 13 years. During that time, over 22,000 field tests have taken place and over 50 products have been reviewed and moved into the commercial marketplace. The system for evaluation of environmental effects of products as they are developed has evolved over time through intentional and consistent work with the scientific community and scientists at the

regulatory agencies. The National Academy of Sciences was instrumental in determining the approach to reviewing field tests through its landmark "Field Testing of Genetically Modified Organisms: Framework for Decisions," published in 1989. The scientific societies have also provided a variety of perspectives on particular issues over the years. In addition, the international regulatory and scientific community has worked in a regular manner to identify, evaluate and scrutinize regulatory approaches and analyses.

The inseparable nature of scientific advancement and regulatory review dictates that the regulatory system must follow the advancements in science and work to keep abreast and ahead of product development to assure the safety of products that are released into the marketplace. Dozens of scientific meetings, workshops, proceedings, publications and research grants have occurred over the past decade to define the broad approaches to review of transgenic plants as well as to address specific issues associated with certain products or types of products. Of necessity, the scope of issues and the approaches to address them evolve as scientific information becomes available and new products are developed. As a result, U.S. regulatory officials have never made a claim that all products of biotechnology are safe, but the regulatory agencies do stand behind the products they have reviewed and determined to be safe.

With the advent of large commercial scale plantings of transgenic plants and their potential for use not only in the United States but also globally, concern over the adequacy of the scope and depth of the review of these plants has grown. In addition, issues have arisen in the scientific community and events covered by the media, civil society, or the general public that have added to this concern. The public does not generally have a clear understanding of agriculture and the consequences of the use of the technology in the agroecosystem as well as potentially on unmanaged environments. In addition, the effects of particular products over time in the environment are not well understood. There is a general inability to distinguish between scientific/biological/ecological issues and a wide range of other important concerns. This project, however, will focus on the scientific issues relevant to a determination of safety or risk. Such an understanding is important as the basis for any other discussion.

APHIS regulations, promulgated under the Plant Quarantine Act and the Federal Plant Pest Act, regulate certain[1] genetically engineered organisms that are imported, moved interstate, or released into the environment if either the donor organism, recipient organism, vector or vector agent used in engineering the organism belongs to a specific taxonomic group and is also a plant pest; if it is unclassified; or, if APHIS has reason to believe that the genetically engineered organism presents a plant pest risk. Once deemed a regulated article, the organism remains under APHIS oversight unless a petition for deregulation is granted.

Environmental issues for crop plants for traditional uses such as food, feed, fiber and horticulture have been framed, defined, and analyzed using the combined expertise and approaches of breeders, agricultural scientists, ecologists, and regulatory scientists. The issues have been framed

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[1]Some organisms may not be regulated by APHIS. For example, if a single corn gene were reinserted back into corn using the bolistic method, it might not fall under APHIS authority. This is determined case- by-case. The Agency recommends that it be contacted to determine whether an organism is regulated. An opinion letter can be obtained from the Agency to clarify the status of the organism.

so that they should be relevant at any scale and to be the same no matter what the stage of planting, whether initial tests, developmental tests, or commercial plantings. However, their probability of occurrence increases with increasing scale. Familiarity with the host plant, the environment, and the introduced trait(s) forms the baseline for the analysis of potential risks. Much of this approach, including the concept of familiarity were identified in the 1989 NAS report and internationally through organizations such as the Organization for Economic Cooperation and Development (OECD). The OECD identified issues such as gene transfer, weediness, non-target effects (trait effects), genotypic and phenotypic variability, vector and pathogenic material effects, and worker safety effects. Consequently, these are the primary issues that are evaluated in any particular case to determine if the possibility of a consequence exists.

After several years of laboratory and field testing, a developer may decide to commercialize the genetically engineered variety and petition APHIS to be released from regulatory oversight. In other words, the developer will submit a petition for APHIS' determination of non-regulated status. Upon receipt of a petition, APHIS thoroughly evaluates the scientific information provided for technical completeness. Specifically, APHIS examines the biology and genetics of the plant, the nature and origin of the genetic material used, possible effects on other organisms in the environment and agricultural products, and all field test reports. Depending upon the particular plant line, APHIS evaluates a variety of potential effects such as: 1) the potential for creating plant pest risk; 2) disease and pest susceptibilities; 3) the expression of gene products, new enzymes, or changes to plant metabolism; 4) potential for weediness, and possible impacts on sexually compatible plants; 5) changes to agricultural or cultivation practices; 6) potential effects on nontarget organisms, including humans; 7) potential effects on other agricultural products; and 8) the potential for gene transfer to other types of organisms.

APHIS also completes an environmental assessment under the National Environmental Policy Act (NEPA) of the new variety to ensure the plant poses no significant risk to the environment, other plants, or non-target species, including humans. Major Federal actions, which have included consideration of permit requests, notifications, or petitions for deregulation are subject to NEPA. For petitions, the agency evaluates all available scientific information, including the information provided by the developer in the petition. In order to approve the petition, the Agency has at a minimum determined that the new transgenic plant: 1) exhibits no plant pathogenic properties; 2) is no more likely to become a weed than the non-engineered plant; 3) is not likely to increase the weediness of any other plant with which it is sexually compatible; 4) will not cause damage to processed agricultural commodities; and 5) is not likely to harm other organisms that are beneficial to agriculture. Other relevant findings may also be reached for individual determinations of nonregulated status.
APHIS has granted petitions for deregulation for transgenic varieties of 13 crops including: sugarbeet, chicory, corn cotton, flax, melon, papaya, potato, rapeseed, rice, soybean, squash, and tomato. A variety of traits have been engineered into these crops including predominantly herbicide tolerance (glyphosate, glufosinate, and sulfonylurea), lepidopteran and coleopteran resistance (utilizing *Bacillus thuringiensis*), and virus resistance. Other agronomic and product quality traits have also been introduced such as male sterility, delayed or altered fruit ripening, and altered oil profile. These are the types of traits that plant breeders have traditionally sought to

incorporate into crop varieties and with which the scientific and plant breeding community has significant experience.

It is anticipated that the Environmental Protection Agency will be interested in and involved in certain of the above indicated sections of the study.

ANTICIPATED RESULTS

This first study should provide the agency with a report containing a comprehensive review of the scientific basis for the evaluation of current plant products, including findings and recommendations. In addition, the study should indicate whether the appropriate questions are being asked and addressed. Based on this review, recommendations as to data requirements either generally or in specific cases or categories should be included. Any recommendations for lessening of information requirements based upon experience and familiarity should also be included. In addition, the study should indicate whether certain parameters should be monitored after commercialization to determine whether identified potential effects occur to any significant degree and to indicate if any types of relevant long term effects are not currently considered in the regulatory evaluation. Agency officials anticipate using the results of the study to identify potential changes in regulations and reviews that might strengthen current evaluations of transgenic plants to assure that appropriate issues are identified and addressed in assuring agricultural and environmental safety.

The report will be subject to standard NRC review procedures and prepared in a sufficient quantity to ensure distribution to sponsors, professional societies, industry and relevant organizations interested in environmental risk assessment of transgenic plants. It will also be available on the Internet and linked to the NRC homepage on the World Wide Web.

FEDERAL ADVISORY COMMITTEE ACT (FACA)

The Academy has developed interim policies and procedures to implement Section 15 of the Federal Advisory Committee Act, 5 U.S.C. App. Part 15. Section 15 includes certain requirements regarding public access and conflicts of interest that are applicable to agreements under which the Academy, using a committee, provides advice or recommendations to a Federal agency. In accordance with Section 15 of FACA, the Academy shall submit to the government sponsor(s) following delivery of each applicable report a certification that the policies and procedures of the Academy that implement contract/grant/cooperative agreement with respect to the applicable report.

PUBLIC INFORMATION ABOUT THE PROJECT

In order to afford the public greater knowledge of the Academy activities and an opportunity to provide comments on those activities, the Academy may post on its website (http://www.nas.edu) the following information as appropriate under its procedures: (1) notices of meetings open to the public: (2) brief descriptions of projects; (3) subcommittee appointments, if any (including

biographies of subcommittee members); (4) report information; and (5) any other pertinent information.

ESTIMATED COST

The estimated cost of this activity for a 18-month period is $400,000. All of this amount has been received.

Origin: External; Federal Executive; Informal
Keywords: transgenic plants; risk assessment; regulation; biosafety